

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New)	NOTICE OF ADOPTION,
Rules I through IX, the amendment of)	AMENDMENT, AND REPEAL
ARM 37.81.104, 37.81.301, 37.81.304,)	
37.81.307, 37.81.310, 37.81.318,)	
37.81.322, 37.81.338, 37.81.346, and)	
the repeal of ARM 37.81.9004,)	
37.81.9005, 37.81.9006, 37.81.9009,)	
and 37.81.9010 pertaining to the)	
Pharmacy Access Prescription Drug)	
Benefit Program (Big Sky Rx))	

TO: All Interested Persons

1. On March 13, 2008, the Department of Public Health and Human Services published MAR Notice No. 37-433 pertaining to the public hearing on the proposed adoption, amendment, and repeal of the above-stated rules, at page 457 of the 2008 Montana Administrative Register, issue number 5.

2. The department has adopted New Rule I (37.81.1001), Rule III, (37.81.1005), Rule IV (37.81.1008), Rule V (37.81.1009), Rule VI (37.81.1012), Rule VII (37.81.1013), Rule VIII (37.81.1020), and Rule IX (37.81.1018) as proposed.

3. The department has amended ARM 37.81.104, 37.81.301, 37.81.304, 37.81.307, 37.81.310, 37.81.318, 37.81.322, and 37.81.338, and repealed ARM 37.81.9004, 37.81.9005, 37.81.9006, 37.81.9009, and 37.81.9010 as proposed.

4. The department has adopted the following rule as proposed with the following changes from the original proposal. Matter to be added is underlined. Matter to be deleted is interlined.

RULE II (ARM 37.81.1002) RULE DEFINITIONS In addition to the definitions in 53-6-1001, MCA, the following definitions apply to this chapter:

(1) and (2) remain as proposed.

(3) "Chronic disease" means a condition or disease of long duration and generally slow progression that requires long term drug treatment such as cardiovascular disease, chronic respiratory disease, diabetes mellitus, and geriatric issues arthritis, epilepsy, cancer, osteoporosis, depression, anxiety, bipolar disorder, or schizophrenia.

(4) through (13) remain as proposed.

AUTH: 53-2-201, 53-6-1006, MCA

IMP: 53-2-201, 53-6-1006, MCA

5. The department has amended the following rule as proposed with the following changes from the original proposal. Matter to be added is underlined. Matter to be deleted is interlined.

37.81.346 BIG SKY RX PDP MEMORANDUM OF UNDERSTANDING (MOU) AND BUSINESS ASSOCIATES AGREEMENT (BAA) (1) An insurer receiving direct payment of all or part of a PDP premium from the state on behalf of an enrollee must enter into a Memorandum of Understanding (MOU) ~~and~~ or Business Associates Agreement (BAA) with the department.

AUTH: 53-2-201, 53-6-1004, MCA

IMP: 53-2-201, 53-6-1001, 53-6-1004, 53-6-1005, MCA

6. Due to a typographical error, the department is amending ARM 37.81.346 to change the word "and" to "or" in the requirement for an insurer receiving a PDP payment to enter into a contract with the department. Either a Memorandum of Understanding or a Business Associates Agreement will be sufficient to satisfy the requirement.

7. The department has thoroughly considered all commentary received. The comments received and the department's response to each follow:

COMMENT #1: The way the definition of "chronic disease" is written could be interpreted to limit the diseases specified by the definition (cardiovascular disease, chronic respiratory disease, diabetes, geriatric issues). These diseases could be included as examples, but PharmAssist benefits should not be limited to those. There are many other diseases or conditions that qualify as chronic and require long-term drug treatment. Patients with these diseases or conditions would benefit from a PharmAssist consultation. Additional examples might include arthritis, epilepsy, cancer, osteoporosis, and mental illnesses (depression, anxiety, bipolar disorder, and schizophrenia). The use of the term "geriatric issues" is ambiguous and may benefit from a clearer definition.

RESPONSE: The department agrees with the commentor. The original intent was not to limit "chronic disease" to the diseases in the definition but to give examples. Therefore, the department will adjust the rule language to clearly state that the listed disease states are just examples of what could be considered a "chronic disease".

8. The department intends these rules to be applied retroactively to July 1, 2007. There is no detrimental effect caused by applying these rules retroactively.

/s/ John Koch
Rule Reviewer

/s/ Joan Miles
Director, Public Health and
Human Services

Certified to the Secretary of State April 28, 2008.